

Table

Combat Ready Clamp data in axillary use

Iteration	Efficacy: yes/no	Shoulder position	Handle turn number	
			On	Off
1	Yes	Abduction, external rotation	4	4
2	Yes	Abduction, external rotation	4	4
3	Yes	Abduction, external rotation	4	4
4	Yes	Abduction, external rotation	5	4
5	Yes	Abduction, external rotation	5	6
6	Yes	Abduction, external rotation	6	5
7	Yes	Abduction, external rotation	6	5
8	Yes	Abduction, external rotation	6	6
9	Yes	Abduction, external rotation	6	6
10	Yes	Abduction, external rotation	10	4
11	Yes	Abduction, internal rotation	5	4
12	Yes	Abduction, internal rotation	4	4
13	Yes	Abduction, internal rotation	3	3
14	Yes	Abduction, internal rotation	4	4
15	Yes	Abduction, internal rotation	5	4

manuscript preparation. Chris Murphy, Jason Cauley, and Steve Stutsman of Combat Medical Systems provided the Combat Ready Clamp drawings and instructions.

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Laboratory assessment of out-of-hospital interventions to control junctional bleeding from the groin in a manikin model[☆]

To the Editor,

Junctional body regions between the trunk and its appendages, such as the groin, are too proximal for a regular limb tourniquet to fit [1,2]. Not since 1993's Black Hawk Down has junctional hemorrhage control become such a hot topic in military casualty care [1–7]. In February 2013, the US military's Task Force Medical Afghanistan requested a fill of a gap in junctional hemorrhage control as an urgent operational need, meaning that junctional hemorrhage control devices should be considered urgently to fill a gap in medical care in war. A small but growing body of evidence indicates that hemorrhage control can be attained out-of-hospital with mechanical compression, using such interventions as medical devices, on a pressure point proximal to a bleeding wound [3–9]. To evaluate laboratory use of junctional hemorrhage control interventions, we gathered data on stopping groin bleeding in a manikin model to understand the plausibility of such interventions for future human subject research.

Under an approved protocol, we tested efficacy of interventions in a manikin designed to train medics in out-of-hospital hemorrhage control (Combat Ready Clamp [CRoC] Trainer Manikin, Operative Experience, Inc, North East, MD). We filled the blood reservoir with 4 liters of water; we refilled the reservoir after 5 iterations or 1.5 liters of lost fluid, whichever came first. The manikin had a right-groin gunshot wound through the proximal thigh where the common femoral artery flow was controllable by skin compression over it at the level of the inguinal fold. There was 3 cm between the pressure point where compression was applied and the proximal extent of the wound. Interventions were timed, blood loss was measured, and efficacy was noted. Efficacy was operationally defined as visually stopped flow into the wound from the vessel lumen. Pearls and pitfalls of intervention use were recorded.

Interventions to control hemorrhage included medical device use, manual or digital compression, and improvised use of a rock-like kettlebell (to simulate a rock used in care on the battlefield in a case recorded in the Department of Defense Trauma Registry in 2012). Interventions included digital (finger) compression, manual compression (heel of the hand), knee compression, compression by a 50-lb kettlebell (Hampton Fitness Products, Ventura, CA), and medical device use (Combat Ready Clamp, CRoC, Combat Medical Systems, Fayetteville, NC; SAM Junctional Tourniquet, SAM, SAM Medical Products, Portland, OR; Junctional Emergency Treatment Tool, JETT, North American Rescue Products, Greer, SC; Abdominal Aortic Tourniquet, AAT, Compression Works, Hoover, AL).

The first device assessed was the CRoC which, of the devices studied, was cleared first by the US Food and Drug Administration on August 11, 2010. The first setting of the evaluation (which was for the CRoC) was in a simulation center as previously reported with three to five people, and the other setting of the evaluation was on a table with one to three people [5]. The data from that initial setting is included here for comparison of time to stop bleeding, blood loss volume, and device efficacy [5]. Since the blood loss rate was non-linear (as it is in real situations for casualties because bleeding is brisker initially rather than later), we did not refill the bladder after each iteration. The

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manikin was not designed to differentiate between performance of devices, so we only compared results to acceptable benchmarks. The benchmark for time to stop bleeding was 300 seconds (s), and the benchmark for blood loss was a normal adult male blood volume, 5 L.

Hemorrhage was controlled with 100% efficacy in the manikin model for each intervention. The times to stop bleeding and volumes of blood lost were acceptable for all devices and iterations (Figs. 1 and 2; Tables 1 and 2). Advantages and disadvantages were learned with experience in the use of each intervention (Table 3). Traits of interventions varied through wide ranges (Table 4).

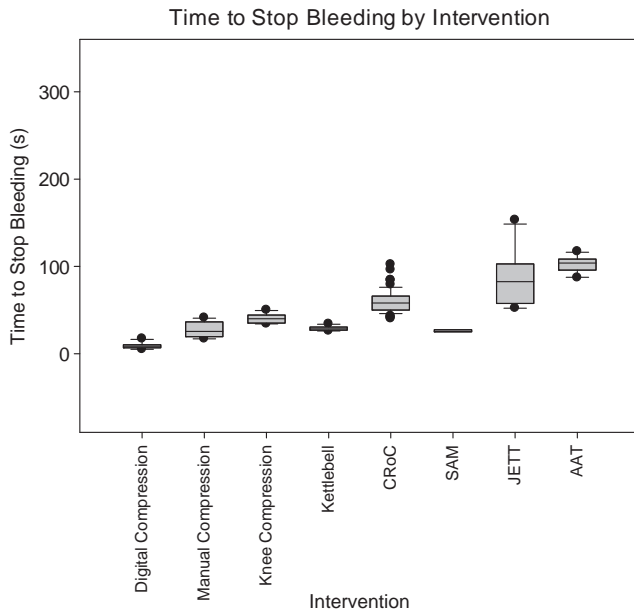


Fig. 1. Times to stop bleeding by intervention. All interventions had similar times to stop bleeding. Vertical box plots have 25th and 75th percentiles as box bottoms and tops, respectively, and if present the 5th and 95th percentiles are whiskers and outliers are black data points. The median is a black line across the box.

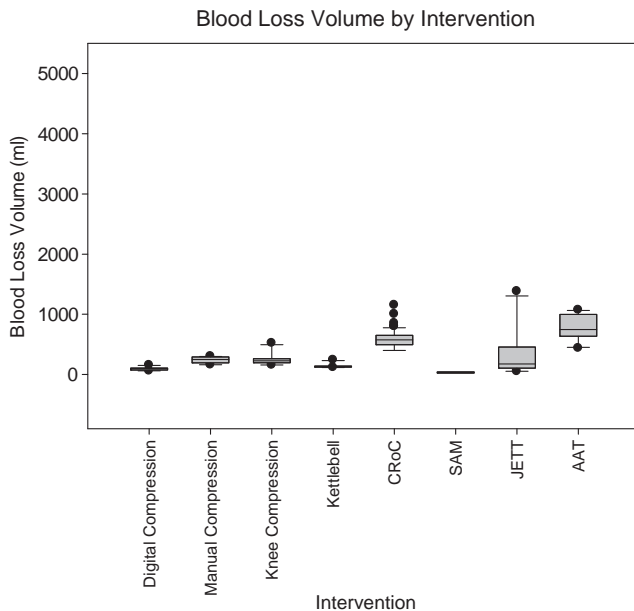


Fig. 2. Blood loss volume by intervention. All interventions had similar blood loss volumes. Vertical box plots have 25th and 75th percentiles as box bottoms and tops, respectively, and if present the 5th and 95th percentiles are whiskers and outliers are black data points. The median is a black line across the box.

Table 1

Blood loss volume data by intervention

Intervention	Iterations (N)	Median blood loss (ml)	Average blood loss (mL)	Minimum blood loss (mL)	Maximum blood loss (ml)
Digital compression	10	98	96	60	155
Manual compression	10	24	239	160	300
Knee compression	10	228	251	155	520
Kettlebell	10	128	140	115	240
CRoC	54	575	581	400	1150
SAM	6	28	35	21	80
JETT	10	175	342	50	1380
AAT	10	748	787	435	1070

SAM indicates SAM junctional tourniquet; JETT, junctional emergency treatment tool; AAT, abdominal aortic tourniquet.

Table 2

Time to stop bleeding data by intervention

Intervention	Iterations (N)	Median time (s)	Average time (s)	Minimum time (s)	Maximum time (s)
Digital compression	10	8	9	5	17
Manual compression	10	26	27	17	41
Knee compression	10	40	40	34	50
Kettlebell	10	29	29	26	34
CRoC	54	58	59	40	102
SAM	6	26	26	25	29
JETT	10	31	41	21	80
AAT	10	104	102	87	117

Table 3

Advantages and disadvantages of interventions learned in initial laboratory use

Intervention	Advantages	Disadvantages
Digital compression	Fast, easiest to target, 1-handed	Smallest muscles tire fastest
Manual compression	Heels of hands work quickly	If 2 hands are used, no hand is free
Knee compression	Powerful, sustained, no hands	Clumsy, can obscure wound
Kettlebell	Fast, rounded edges, frees 1 hand	Heavy, tilts, 1 hand to steady
CRoC	First available, best known device	Disc can fall, has the most steps
SAM	Fast, may use binder on pelvis	Newest, least known device
JETT	Harness may splint a pelvis fracture	Disc can fall, 2 straps, 2 discs
AAT	Targets pressure point broadly	May block vena cava

Table 4

Intervention data by added weight carried and storage displacement

Intervention	Added weight carried(g)	Storage volume(L)
Digital compression	0	0
Manual compression	0	0
Knee compression	0	0
Kettlebell	22680	3.5
CRoC	799	0.8
SAM	499	1.5
JETT	651	1.6
AAT	485	1.4

Added weight carried is in grams.

The main finding of the present study was that the interventions assessed could plausibly be used for human subject research and out-of-hospital clinical care. All interventions were successful with short times to stop bleeding and low volumes of blood lost. No major safety issues were found; however, minor differences in advantages and disadvantages among the interventions evaluated may influence different potential users who may have their own specific strategies and their own priorities.

The design was limited in its purpose to provide plausibility evidence in consideration of conducting future human subject research. While the present report may not translate fully in an in vivo model, it may increase awareness of hemorrhage control interventions.

Future work may include studies to evidence differential performance of hemorrhage control interventions head to head in other models such as assessments in human subjects.

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Appropriate sample dilution for troponin I testing

To the Editor,

The assessment of cardiospecific troponin, either troponin I (TnI) or T, is a mainstay for diagnosing acute myocardial infarction as well as for detecting a variety of nonischemic myocardial injuries [1]. The finding of highly increased concentrations of cardiospecific troponin(s), exceeding the upper detection limit of the immunoassay, is a rare but challenging occurrence [2]. According to available recommendations [3], sample dilution may be systematically required in this circumstance, for accurate calculation of kinetics and delta variation. There is evidence, however, that the material used for diluting samples may produce biased results, with negative influence on the clinical decision making. In particular, Er et al [4] previously reported that results of TnI measured with the AccuTnI reagent on UniCel DxI (Beckman Coulter, Inc, Chaska, MN) were significantly biased when samples were diluted with distilled water (ie, from 11.2% to 27.0% higher) or isotonic saline (ie, from 5.6% to 19.4% higher) as compared with values obtained on samples treated with sample diluent.

To assess the most suitable dilution material for the AccuTnI reagent, we randomly selected 7 routine plasma samples with AccuTnI concentrations comprised between 3.45 and 6.91 $\mu\text{g/L}$, which were diluted at fixed ratios (1:2 and 1:5) with instrument wash buffer, isotonic saline, or a negative pool of plasmas displaying AccuTnI concentration lower than the analytical sensitivity of the assay (ie, <0.01 $\mu\text{g/L}$). The undiluted samples, along with the 1:2 and 1:5 dilutions, were then reassessed for AccuTnI in duplicate, in an identical analytical session, on the same UniCel DxI analyzer. Results of duplicate testing were averaged, and difference of values was assessed with Bland-Altman plot analysis, using Analyse-it for Microsoft Excel (Analyse-it Software Ltd, Leeds, UK). The study was based on preexisting samples obtained after routine analysis was completed, and no informed consent or ethics committee approval was, hence, necessary.

The results of this study are shown in the Table. No statistically significant bias was observed when samples were diluted with either wash buffer or isotonic saline, whereas a statistically significant decrease of AccuTnI values was observed using a patient's plasma with immeasurable values of TnI. The lowest bias, comprised between 2.0% and 2.1%, was observed using isotonic saline.

Table

Results of TnI testing with AccuTnI on UniCel DxI in plasma samples diluted with different materials

	Mean value (95% CI)	Mean bias (95% CI)	P
Undiluted sample	4.60 (2.85–6.35)		
Wash buffer (1:2 dilution)	4.65 (3.17–6.12)	2.0% (–5.8% to 9.7%)	.52
Wash buffer (1:5 dilution)	4.84 (3.11–6.58)	5.3% (–9.0% to 19.5%)	.36
Isotonic saline (1:2 dilution)	4.65 (3.21–6.09)	2.0% (–7.5% to 11.6%)	.58
Isotonic saline (1:5 dilution)	4.70 (2.94–6.46)	2.1% (–9.1% to 13.3%)	.63
Plasma (1:2 dilution)	4.25 (2.67–5.84)	–7.8% (–16.6% to 1.0%)	.049
Plasma (1:5 dilution)	4.25 (2.55–5.95)	–8.5% (–16.8% to –0.1%)	.038

Abbreviation: CI, confidence interval.